

K091001

**5. 510(K) SUMMARY**

[As Required by 21 CFR 807.92]  
Summary of Safety and Effectiveness

**Preparation date** April 2<sup>nd</sup>, 2009 JUN 29 2009

**Submitter**

**Name** INTRASENSE

**Registration number** 3006546169

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**Contact Persons**

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**Device name**

**Common Name** System, Image Processing

**Trade Name** MYRIAN

**Model number** N/A

**Device classification**

**Classification name** System, Image Processing, Radiological

**Code product** LLZ

**Panel** 892

**Regulation number** 892.=2050

**Regulatory class** II

**Predicate devices**

[K052995] Cleared [November 8, 2005] [General Electric Medical Systems] [Advantage Workstation Version 4.3], manufactured by [General Electric Medical Systems]

[K061624] Cleared [June 27, 2006] [Vital Images, Inc.] [Vitrea2 Version 3.9], manufactured by [Vital Images, Inc.]

[K082228] Cleared [July 31, 2008] [Pathfinder Therapeutics, Inc] [Planisight Linasys™], manufactured by [Pathfinder Therapeutics, Inc]

[K071000] Cleared [May 14, 2007] [intrasense], manufactured by [intrasense SAS]

**Description**

The Myrian® System is a software suite providing the following services:

- Import of DICOM files from any DICOM-compliant modality, workstation or PACS.
- Visualization of DICOM images in various standard visualization modes (e.g. MPR, 3D...etc.) with optional image-alignment feature. Creation of OOI (Objects Of Interest) for measurement purpose
- Follow-up of patient examination
- Generation of medical reports
- Export of DICOM images to any format, towards any DICOM entity or recognized media.
- Virtual Cutting surface tool for preoperative evaluation of surgery strategies.

**Explanation of how the device operates**

Myrian® with its modules is designed to run on standard PC hardware, through the installed operating system. The hardware is all "off-the-shelf" standard computer components and may be purchased independently by the end user.

**Intended use**

Myrian is a multi modality medical diagnostic device for the review and analysis of anatomy and pathology in multi-dimensional digital images acquired from a variety of imaging devices. It also includes DICOM communication capabilities and media interchange features (printing, CD burning, storing). It runs on any standard PC including laptops that might be purchased independently by the end user. Typical end users are trained medical professionals..

Myrian includes tools which enable the reviewing physician to provide any selected relevant information for diagnosis, surgery and treatment planning to the referring physician.

These toolsets are categorised as follow:

- Enhanced imaging tools such as:
  - Multi-Planar Reformation (MPR) views in any plane (orthogonal, oblique or curved), 3D views in any rendering mode (MIP, MiniP, Average, Volume Rendering)
  - Cross-sectional or Endoscope Exploration Modes along a centerline (e.g. of a vessel, a colon...etc.)
  - Filet Visualization Mode, to visualize as a flat surface any tubular hollow organ (such as a colon)
- Manual or interactive Objects Of Interest such as :
  - Annotations of Interest, for information or measurement purposes
  - Paths (considered as Annotations of Interest);
  - Regions of Interest, for anatomical and pathological structure isolation (such as liver, spleen, lungs, colon ...etc.) through which any measurement can be performed
  - Points of Interest, for marking areas such as lesions, tumors...etc.
- Reporting tools :

Objects of Interest generates reports which may be viewed and sent to standard film or paper printers or sent electronically to an intranet web server or any other DICOM device.

- Manual or assisted image alignment tools :
  - for multiphasic or time-based image comparisons
  - Cutting Surface Tool – based on ROI - for preoperative evaluation of surgery strategies (such as for the liver).

This device is not indicated for mammography use. Lossy compressed mammography-images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

All Myrian functionalities can be packaged, licensed and marketed as individual modules. The Myrian System allows the OEM customization of both the graphical user interface and the available functionalities, while implying no impact on the system performance or system intended use.

**Performance data**

Performance data were verified versus the requirements of the FDA "Guidance of the Content of Pre Market Submissions for Software Contained in Medical Devices"

User Site Testing and Benchmarking demonstrate that MYRIAN meet the required specifications. No adverse affects have been detected.

**Substantial equivalence summary**

The technological characteristics, features, specifications, materials, mode of operation, and intended use of MYRIAN device are equivalent to those of the predicate devices quoted above.

MYRIAN is the same as the predicate devices in K061624, K052995, K071000 and K082228

The differences that exist between the devices do not raise new issues of safety or effectiveness regarding MYRIAN Device.

It is substantially equivalent in terms of safety and effectiveness to the predicate devices.

The "Substantial Equivalence Decision Making Process" provided by the FDA has been followed, see dedicated section in this document.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 29 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Frederic Banegas  
Chief Technical Officer  
Intrasense  
CAP OMEGA, Rond Point Benjamin Franklin CS 39521  
Montpellier, 34960  
FRANCE

Re: K091001

Trade/Device Name: Myrian  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: June 10, 2009  
Received: June 16, 2009

Dear Mr. Banegas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

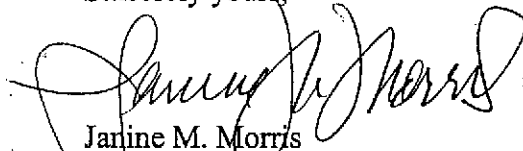
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known):

K091001

Device Name: Myrian

Indications for Use (no change):

Myrian is a multi modality medical diagnostic device. It is aimed at reviewing and analyzing anatomy and pathology. It also includes DICOM communication capabilities and media interchange features (printing, CD burning, storing). It runs on any standard PC including laptops that might be purchased independently by the end user. It provides user a set of tools meant to create and modify objects of interest : points of interest, annotations of interest and volumes of interest.

This device is not indicated for mammography use. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

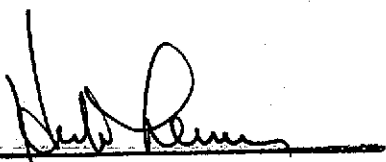
Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K091001